

§ 892.1130

(b) *Classification*. Class I.

[55 FR 48444, Nov. 20, 1990]

§ 892.1130 Nuclear whole body counter.

(a) *Identification*. A nuclear whole body counter is a device intended to measure the amount of radionuclides in the entire body. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

[53 FR 1567, Jan. 20, 1988, as amended at 59 FR 63015, Dec. 7, 1994]

[55 FR 48444, Nov. 20, 1990]

§ 892.1170 Bone densitometer.

(a) *Identification*. A bone densitometer is a device intended for medical purposes to measure bone density and mineral content by x-ray or gamma ray transmission measurements through the bone and adjacent tissues. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification*. Class II.

§ 892.1200 Emission computed tomography system.

(a) *Identification*. An emission computed tomography system is a device intended to detect the location and distribution of gamma ray- and positron-emitting radionuclides in the body and produce cross-sectional images through computer reconstruction of the data. This generic type of device may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(b) *Classification*. Class II.

§ 892.1220 Fluorescent scanner.

(a) *Identification*. A fluorescent scanner is a device intended to measure the induced fluorescent radiation in the body by exposing the body to certain x-rays or low-energy gamma rays. This generic type of device may include signal analysis and display equipment, pa-

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tient and equipment supports, component parts and accessories.

(b) *Classification*. Class II.

§ 892.1300 Nuclear rectilinear scanner.

(a) *Identification*. A nuclear rectilinear scanner is a device intended to image the distribution of radionuclides in the body by means of a detector (or detectors) whose position moves in two directions with respect to the patient. This generic type of device may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(b) *Classification*. Class I.

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§ 892.1310 Nuclear tomography system.

(a) *Identification*. A nuclear tomography system is a device intended to detect nuclear radiation in the body and produce images of a specific cross-sectional plane of the body by blurring or eliminating detail from other planes. This generic type of devices may include signal analysis and display equipment, patient and equipment supports, radionuclide anatomical markers, component parts, and accessories.

(b) *Classification*. Class II.

§ 892.1320 Nuclear uptake probe.

(a) *Identification*. A nuclear uptake probe is a device intended to measure the amount of radionuclide taken up by a particular organ or body region. This generic type of device may include a single or multiple detector probe, signal analysis and display equipment, patient and equipment supports, component parts, and accessories.

(b) *Classification*. Class I.

[55 FR 48444, Nov. 20, 1990]

§ 892.1330 Nuclear whole body scanner.

(a) *Identification*. A nuclear whole body scanner is a device intended to measure and image the distribution of radionuclides in the body by means of a wide-aperture detector whose position moves in one direction with respect to the patient. This generic type of device may include signal analysis